REMARKS

I. Amendments and Status of Claims

By this amendment, the specification and claims are amended. Pages 44 and 45 of the substitute specification are amended to place quotations around the terms "amino acid," "host," and "pharmaceutically acceptable salt" or "pharmaceutically acceptable prodrug." Claims 1-37 are under consideration in this application. Claims 1-12 were withdrawn from consideration by the Examiner as being directed to non-elected subject matter. Office Action at page 2. In the Office Action, the Examiner indicates that claim 20 is allowed. *Id.* at page 7. Applicant acknowledges and appreciates the Examiner's indication of this allowable subject matter.

By this amendment, claims 13, 18, 19, 21, 22, and 23 are amended. Claims 13 and 18 are amended to add provisos. In claim 18, compounds of the general formula 2 (A-D), 3 (A-B), 4 (A-B), 5 (A-B), 6 (A-B), 7 (A-C), and 8 (A) are deleted and added as new claim 26 to more particularly define the invention. Claim 18 is further amended to delete the definitions of substituents contained only in the deleted compounds. Claim 19 is amended to narrow the definition of Z' and to delete the definition of R^2, as R^2 is not contained in the structure claimed. Claim 21 is amended to delete the compound of formula 1 (K). Claims 22 and 23 are amended to add dependencies on new claims 25-27, 29-30, and 33-37.

New claims 25-37 are added. Support for new claim 25 can be found, for example, on pages 14 and 15 of the substitute specification. Support for new claim 26 can be found, for example, on page 15, line 13, to page 18, line 3, of the substitute specification and in original claim 18. Support for new claims 27-29 can be found, for

example, on page 28, line 7, to page 33, line 2, of the substitute specification. Support for new claim 30 can be found, for example, on page 33, line 3, to page 34, line 2, of the substitute specification. Support for new claims 31 and 32 can be found, for example, on page 34 of the substitute specification and in original claim 21. Support for new claim 33 can be found, for example, on page 18, lines 8-14, of the substitute specification and in claim 19 as originally filed. Support for new claims 34 and 35 may be found, for example, on page 66, lines 4-6, and Scheme 1 of the substitute specification. Support for new claims 36 and 37 may be found, for example, on pages 75 and 76 (Scheme 10) of the substitute specification, Examples 48 and 49, structure 1 (I) on page 33 of the substitute specification, and structures 1 (L) and 1 (M) on page 34 of the substitute specification. These new claims recite additional compounds within the currently elected and examined subject matter. Applicant reserves the right to add corresponding process of use claims once the process claims are rejoined. No new matter has been added.

II. Election/Restriction Requirement

The Examiner acknowledges Applicant's election with traverse of Group XVI, namely claims 13-24, but finds Applicant's argument that the search for products of Groups [IX-XVI] would also uncover the process of use of Groups [I-VIII] unpersuasive. *See* Office Action at page 2. The Examiner contends that "because many products can be used with the process of Groups [I-VIII] . . . the search for the products of Groups [IX-XVI] will not necessarily yield the process of Groups [I-VIII]. *Id.* Applicant respectfully points out that only the compounds of Groups [IX-XVI] can be used in the process of Groups [I-VIII] since those processes are limited to the products. Therefore

the process claims of Groups [I-VIII] should be rejoined once the product claims of Groups [IX-XVI] are found allowable.

In response to Applicant's election with traverse of the species of a compound of formula (I), namely formula 1(J), the Examiner maintains his position "that there is a search burden for the compounds of formula (I)." *Id.* at page 3. Applicant continues to traverse based on the reasons set forth in the reply filed on January 3, 2007, and further notes that since the elected species was found to be free of prior art, the search has already been broadened to the compound of formula (I).

III. Oath/Declaration

The Examiner objects to the declarations filed in this application, asserting that the declarations do not "identify the citizenship of each inventor" since "Chinese, Belgian, Japanese, Egyption, Korean, and French are not proper countries of citizenship." *Id.* at page 4. Applicant respectfully requests reconsideration. The inventors' citizenship has been correctly identified in their original declarations. M.P.E.P. § 605.01 states that "[t]he statute (35 U.S.C. § 115) requires an applicant in a nonprovisional application, to state his or her citizenship." The rule does not specify that an applicant list the official name of the country of which he or she is a citizen. In fact, the Office's sample Declaration Form PTO/SB/01 does not call for the "country of citizenship" but simply citizenship. Since the declarations used in this application were based on the Office's form, the inventors stated their citizenship instead of naming their country of citizenship. Since no doubt can exist as to the inventors' countries of citizenship, Applicant respectfully requests that this objection be withdrawn.

IV. Specification

The Examiner objects to the specification because of the omission of quotation marks around the terms "amino acid" in line 23 on page 44 and "host" in line 10 on page 45. Office Action at page 4. Line 23 on page 44 of the specification is amended to recite "amino acid" and line 10 on page 45 is amended to recite "host." In addition, the Examiner asserts that quotation marks around the term "pharmaceutically acceptable salt or prodrug" should be "pharmaceutically acceptable salt" or "prodrug" in line 21 on page 45. *Id.* Line 21 on page 45 is amended to recite "pharmaceutically acceptable salt" or "pharmaceutically acceptable prodrug." In view of the amendments to the specification, Applicant respectfully submits that these objections are moot.

V. Rejection under 35 U.S.C. § 102

The Examiner rejects claims 13-14, 19, and 21 under 35 U.S.C. § 102(b) as allegedly being anticipated by Sasaki et al. (Journal of Organic Chemistry, 1976, vol. 41, no. 7, pp. 1100-1104) ("Sasaki et al."). The Examiner asserts that Sasaki et al. "teach Compound 4, 9,5'-cyclo-3-β-D-ribofuranosyl-8-azaxanthine, which meets the limitations of the instant claims." Office Action at page 5.

Applicant respectfully requests the withdrawal of this rejection in view of the instant amendments. Claim 13 is amended to exclude Compound 4 by stating that "when R^2 is CR'_2, W is O, $R^{4'}$ is hydroxyl, R^4 is hydrogen, $R^{5'}$ is hydroxyl, and R^5 is hydrogen, the bicyclic ring formed is not . . . an 8-azaxanthinyl ring wherein R^2 and R^3 form together the five-membered ring." Claim 14 depends on claim 13 so the proviso also obviates the rejection of claim 14. Claim 19 is amended to narrow the definition of Z' to CH or CX. New claim 33 further encompasses compounds of the formula recited

in claim 19 wherein Z' is defined as CH, CX, or N and Z is defined as CH or CX. Claim 21 is amended to delete the compound of formula 1 (K).

Applicant also respectfully points out that Sasaki et al.'s Compound 4 is shown in keto tautomer form. Since the keto tautomer form may lie in equilibrium with the hydroxy tautomer form, claim 18 is amended to exclude the hydroxy tautomer form by stating "that for compounds of formula 1 (B), when X is OH, Y is O, W is O, $R^{4'}$ is hydroxyl, R^4 is hydrogen, $R^{5'}$ is hydroxyl, and R^5 is hydrogen, Z is not N." A similar proviso is added to the definition of a compound of formula 1 (F) in new claim 27. Applicant also amends claim 13 to exclude a hydroxy tautomer that may be in equilibrium with the keto form xanthosine derivative 12 depicted in Miles et al. (Journal of the American Chemical Society, 1971, vol. 93, no. 7, pp. 1600-1608).

The Examiner rejects claim 18 under 35 U.S.C. § 102(b) as allegedly anticipated by Morin et al. (Chemical Research in Toxicology, 1995, vol. 8, pp. 792-799) ("Morin et al."). The Examiner asserts that "Morin et al. teach Compound 1, 5'-amino-2',5'-dideoxyguanosine, which meets the limitation of the instant claim (page 794, figure 1)." Office Action at page 5. Applicant submits that Compound 1, 5'-amino-2', 5'-dideoxyguanosine (5'-NH_2dGuo) is not a cyclic nucleoside within the scope of any of the compounds of claim 18. *See* Morin et al., page 797, Figure 7. Figure 1 on page 794 of Morin et al. shows the HPLC elution profile of the products of benzophenone-mediated photosensitization of 5'-amino-2',5'-dideoxyguanosine in aerated aqueous solution on an ODS column. The structure shown in Figure 1 is not Compound 1, but Compound 8, 9-oxa-2,4-diazabicyclo[4.2.1]non-2-en-7-ol, 3-amino- (1R-*exo*). Morin et al., page 794, Figures 1 and 2. Compounds of formula 8 (A) are encompassed by new claim 26,

which provides "for compounds of formula 8 (A), when R^2 is NH, R^a is hydrogen, W is O, and R^4, R^5, and $R^{5'}$ are hydrogen, $R^{4'}$ is not hydroxyl," thereby excluding Morin et al.'s compound. Likewise, new claim 29 provides that "for compounds of formula 8 (B), when R^2 is NH, R^a is hydrogen, and R^4, R^5, and $R^{5'}$ are hydrogen, $R^{4'}$ is not hydroxyl." Claim 13 is also amended to provide that "when W is O, $R^{4'}$ is hydroxyl, and R^1, R^3, R^4, R^5, and $R^{5'}$ are hydrogen, R^2 is not NH." Applicant respectfully requests the withdrawal of this rejection.

VI. Rejection under 35 U.S.C. § 103

The Examiner rejects claim 22 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Sasaki et al. The Examiner asserts that "Sasaki et al. teach Compound 4, 9,5'-cyclo-3-beta-D-ribofuranosyl-8-azaxanthine and that some of the 5-halopyrimidine nucleosides are known to be chemicals of biological interest." Office Action at page 6. The Examiner further contends that "some of the solvents used to make Compound 4, namely ethanol, are considered pharmaceutically acceptable carriers." *Id.* The Examiner then concludes that it would be obvious to make a pharmaceutical composition of Compound 4 with a pharmaceutically acceptable carrier because "Compound 4 has biological activity and . . . compounds with biological activity are routinely made into pharmaceutical compositions with pharmaceutically acceptable carriers." *Id.* Applicant respectfully disagrees.

In making a rejection under 35 U.S.C. § 103, the Examiner has the initial burden to establish a prima facie case of obviousness. *See* M.P.E.P. § 2143. To satisfy this burden, the Examiner must first show that the prior art references teach or suggest all the claimed limitations. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). The

Examiner must also show that there is some suggestion or motivation, either in the references or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. *In re Rouffet*, 149 F.3d 1350, 47 USPQ2d 1453 (Fed. Cir. 1998). The Supreme Court, in *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741, 82 USPQ2d 1385, 1396 (2007), recognized that a showing of "teaching, suggestion, or motivation" could provide helpful insight in determining whether the claimed subject matter is obvious under Section 103(a). In addition, the Supreme Court instructed that "[t]o facilitate review, this analysis should be made explicit." *Id.* (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness")). Following the *KSR* decision, the Office issued a memorandum to its technology center directors on May 3, 2007, indicating that "**in formulating a rejection under 35 U.S.C. § 103(a) based upon a combination of prior art elements, it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed**." (Emphasis in original).

Here, the Examiner has not established a prima facie case of obviousness. Applicant respectfully submits that Sasaki et al. disclose methanol, not ethanol, as the reaction solvent used to make Compound 4. *See* Sasaki et al., p. 1103, preparation of Compound 4. A pharmaceutically acceptable carrier must be capable of being administered to a host without harming the host. One of skill in the art would not administer a compound in methanol to a host since methanol is potentially harmful to a

host. Therefore, the Examiner has not shown that Sasaki et al. teach or suggest a pharmaceutically acceptable carrier nor has he identified why a person of ordinary skill would have combined the prior art elements in the manner claimed. Applicant respectfully requests the withdrawal of this rejection.

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: October 12, 2007

By: 
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